UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,468	04/21/2004	Max R. Motyka	22305	6421

20551 7590 01/26/2007
THORPE NORTH & WESTERN, LLP.
8180 SOUTH 700 EAST, SUITE 200
SANDY, UT 84070

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,468	MOTYKA ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10,13-28 and 30-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-10, 13-28 and 30-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-10, 13-28, and 30-53 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/2006 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamoto et al. (J. Am. Chem. Soc. 1961, 83(22), 4528-4532).

Nakamoto et al. disclose thirty metal chelate compounds including eight different metal-glycine chelates (Abstract; page 4531, Table 1). Nakamoto et al. disclose a

chromium-glycine chelate of the formula: $Cr(NH_2\text{-}CH_2\text{-}COO)_3\ H_20$; thus 3 glycine to 1 chromium ratio (Page 4531, Table 1).

Please note: With respect to the USC 102 rejection above and the rejections to follow, please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' non-GMO metal amino acid chelate composition differs and, if so, to what extent, from that of the discussed reference.

Claim Rejections - 35 USC § 102

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lumb et al. (J. Phys. Chem. 1953, 57(7), 690-693).

Lumb et al. disclose the 1:1 chelate stability constants of calcium (instant claim 3) and glycine (instant claim 2) thus anticipating the instant composition (instant claim 1) (page 692, right column "Chelate Stability Constants; and Table III).

Claim Rejections - 35 USC § 102

Claims 1-3, 5, 17-19, 27-28, 34-36, 41-45 and 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu (US 5,504,055).

Hsu discloses metal amino acid chelates that can deliver high levels of desirable metal ions to plants and human beings (Abstract; Column 1, lines 44-50). Hsu distinctly claims iron, copper, zinc, magnesium and calcium as metal ions and glycine as the amino acid (Column 11, lines 45-52; Column 12; lines 12-14 and 18-24). The mole ratio of metal ion to acid is about 1:2 (Column 2, lines 35-36). Thus, instant claims 1-3 are anticipated. Hsu disclose a composition comprising ferrous iron carbonate/citric acid/glycine to produce an amino acid chelate thus anticipating the addition of citric acid (instant claims 17-19, 27-28 and 50-51) (Column 3, lines 63-67 and column 4, lines 1-14). Hsu provides methods to synthesize the metal amino acid chelate (instant claims 34-36) (Column 3, liens 63-67 and Column 4, lines 1-14, for example). The Examiner interprets the selection of specific reagents by Hsu to produce the metal amino acid chelate as reading upon instant claims 35 and 36. Hsu administered the iron/citrate/glycine chelate to tomato plants (instant claim 43-45) (Column 7, lines 56-67 and column 8, lines 1-13). The Examiner interprets the selection of specific reagents by Hsu to produce the metal amino acid chelate for administration to tomato plants as reading upon instant claims 41-45 and 50-51.

Claim Rejections - 35 USC § 102

Claims 1-3, 5, 17, 20-22, 26-28, 34-36, 41-45, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashmead et al. (US 6,426,424).

Ashmead et al. disclose compositions and methods of preparing amino acid chelates (Abstract). The amino acid ligand to metal molar ratio is from about 1:1 to 4:1 (Instant claim 1) (Column 5, lines 31-35 and column 10, lines 24-25). Ashmead et al. disclose iron, copper zinc manganese, cobalt, magnesium, chromium, and molybdenum as metal ions and provide examples of a ferrous glycine chelate, zinc glycine chelate, manganese glycine chelate, magnesium glycine chelate, copper glycine chelate as well as mixed metal/amino acid chelates in the ratios of amino acid ligand to metal ion of 2:1 to 3:1 (instant claims 2, 3 and 5)(Column 8, lines 8-25 and 48-67; column 9, lines 5-67 and column 10, lines 1-16). Ashmead et al. produced a metal amino acid chelate and added to the composition maltodextrin, corn-starch and cellulose (instant claims 17, 20-22, 26-28 and 34-36 and 41-42) (Column 9, lines 29-32). Applicant defines in the specification that maltodextrins can be both fillers and flow control agents (Instant specification page 14, lines 19-20). Ashmead et al. disclose that the amino acid chelates can be administered to plants by dissolution on leaves or as a soil treatment thus anticipating instant claim 43 (Column 7, lines 53-63). Obtaining metal ions and amino acids to make the composition reads upon instant claims 44 and 45.

Claim Rejections - 35 USC § 102

Claims 1-3, 17-22, 24-28, 43-45, 50-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashmead et al. (US 4,725,427).

Ashmead et al. disclose a vitamin and mineral composition comprising amino acid metal chelate with an amino acid ligand to metal ratio of at least 2:1 and a method of preparing the vitamin and mineral composition (Column 5, line 61; column 11, lines 1-23 and lines 53-59; column 12, lines 1-36). The amino acid chelated minerals are selected from the group consisting of calcium, magnesium, iron, zinc, copper and manganese (Column 12, lines 18-22). Glycine is disclosed as a amino acid ligand (Column 5, lines 64-67). Thus, instant claims 1-3 are anticipated.

A powdered mixture of water soluble vitamins was prepared by blending calcium ascorbate folic acid thiamine mononitrate, sodium salt of riboflavin-5-phosphate, niacinamide pyridoxine HCl, biotin and calcium pantothenate (Column 9, lines 15-21). The powdered mixture was then blended with powdered lactose. The Examiner interprets powdered lactose to be a maltodextrin and the Applicant defines in the specification that maltodextrins can be both fillers and flow control agents (instant claims 17 and 20-22)(Instant specification page 14, lines 19-20). In a separate container, ethanol, propylene glycol, vegetable oil, vitamin A palmitate, vitamin D, vitamin E and cyanocobalamin were mixed until dissolution (instant claim 25) (Column 9, lines 24-34). The water-soluble vitamins were then added to the oil soluble vitamins and blended (Column 9, lines 35-43). To this mixture was added amino acid metal chelates and potassium amino acid complex (instant claims 24-25 and 27-29) (Column

9, lines 44-51). After blending, citric acid (instant claims 18 and 19), potassium bicarbonate and sodium bicarbonate, lime and lemon flavoring and aspartame sweetener (instant claim 26) were added and completely mixed and ultimately granulated (Column 9, lines 52-67). The granules dissolved in water to provide a pleasant tasting flavored drink (instant claims 43-45, 50 and 51) (Column 2, lines 35-40 and column 10, lines 1-5). Ashmead et al. claim the method of preparing the composition (Column 11, lines 53-59 and column 12, lines 1-36). The reference of Ashmead et al. is deemed to meet the limitations of the instant claims 1-3, 17-22, 24-28, 43-45, 50-51 and 53.

Response to arguments:

As stated in the prior action, the Examiner cannot distinguish between the prior art compositions and the instantly claimed invention and, as stated above, that in product-by-process claims, once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show a difference. MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). The prior art references of Lumb and Nakamoto are deemed to make metal amino acid chelates; a process that is not esoteric and that is known to one of ordinary skill such that Nakamoto refers to the process as using "standard procedures". In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' non-GMO metal amino acid chelate composition differs and, if so, to what extent, from that

of the discussed reference. Therefore, with the showing of the reference, the burden of establishing a dfference by objective evidence is shifted to the Applicants.

Applicant has not provided a showing of the differences between the prior art metal amino acid chelates and the instantly claimed metal amino acid chelates. Applicant asserted that the differences between a non-GMO metal amino acid chelate and a GMO metal amino acid chelate relates to the starting materials of which each type has impurities associated with its manufacturing and cultivation processes and the impurities are not the same. It is the Examiner's position that the claims read on a metal amino acid complex and impurities are not recited in the claim language. Furthermore, it is irrelevant if the genetically modified organisms are chemically and structurally different than their non-genetically modified counterparts. The product is still an amino acid. An amino acid is an amino acid.

Applicant's argument that extraction of an amino acid from "two chemically and structurally different sources would provide a product that is inherently chemically different since no product is 100% pure". The Examiner maintains that an amino acid is an amino acid and applicant has not shown a structural difference. Otherwise it would not be the same amino acid.

Applicant asserted that Hsu, Ashmead '424 and Ashmead '427 do not provide a method of preparing or administering a non-GMO metal amino acid chelate composition as described in independent claims 34 and 43. The Examiner respectfully disagrees and points out that there is nothing to suggest that the methods described in the cited references would direct one of ordinary skill in the art to specifically choose a metal or

amino acid from a genetically modified organism. Without clear and convincing evidence, one of ordinary skill in the art would obtain a metal and an amino acid from what the applicant calls a "non-GMO" source, which is inherent in the method.

For these reasons, and those of record, the 35 U.S.C. 102(b) rejections are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al. (US 5,504,055) in view of Cooper et al. (US 6,299,896).

The reference of Hsu et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Hsu et al. do not expressly disclose a composition wherein the formulation additive is a non-GMO flow control agent selected from the group consisting of fumed silica, stearic acid, talc, and combinations thereof.

Cooper et al. teaches a multi-vitamin nutritional supplement (Abstract). When preparing dosage forms incorporating the composition, the nutritional components are normally blended with conventional excipients such as the lubricant stearic acid.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the powder composition of Hsu et al. by adding a stearic acid lubricant as suggested by Cooper et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because stearic acid is a conventional lubricant added to dosage forms known by those of ordinary skill in the art. Cooper et al. disclose powders as a suitable dosage form (Column 9, line 62).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Claim Rejections - 35 USC § 103

Claims 1, 13-17 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead et al. (US 4,725,427) in view of Izumi et al. (Angew. Chem. Int. Ed. Engl. 1978, 17, 176-183).

The reference of Ashmead et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Ashmead et al. do not expressly disclose a composition as in claims 1 or 17 wherein the naturally occurring amino acid used to prepare the amino acid chelates is

prepared by: 1) a method other than protein hydrolysis; 2) synthetically; 3) fermentation; and 4) protein hydrolysis and wherein the protein used in the hydrolysis is non-GMO.

Izumi et al. teach multiple methods of producing amino acids including enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods (Page 176, Table 1; page 177, 2.1 Extraction Method; 2.2 Fermentation Method; page 178, 2.3 Enzymatic method; and page 179, Synthetic Method).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to obtain amino acids via one of the methods suggested by Izumi et al. for the composition of Ashmead et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Izumi et al. state these methods are the recent advances in industrial production of amino acids (Page 176, middle of right column)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Claim Rejections - 35 USC § 103

Claims 34, 37-40, 43 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al. (US 5,504,055) in view of Izumi et al. (Angew. Chem. Int. Ed. Engl. 1978, 17, 76-183).

The reference of Hsu et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Hsu et al. do not expressly disclose a method as in claims 34 and 43 wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by: 1) a method other than protein hydrolysis; 2) synthetically; 3) fermentation; and 4) protein hydrolysis and wherein the protein used in the hydrolysis is non-GMO.

Izumi et al. teach multiple methods of producing amino acids including enzymatic, fermentation, extraction (protein hydrolysis) and synthetic methods (Page 176, Table 1; page 177, 2.1 Extraction Method; 2.2 Fermentation Method; page 178, 2.3 Enzymatic method; and page 179, Synthetic Method).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to obtain amino acids via one of the methods suggested by Izumi et al. for the composition of Hsu et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Izumi et al. state these methods are the recent advances in industrial production of amino acids (Page 176, middle of right column)

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Response to arguments:

Applicant asserted that the cited references do not teach a non-GMO chelate and therefore there can be no *prima facie* case of obviousness. The Examiner cannot agree. The addition of excipients such as flow control agents is obvious to one of ordinary skill in the art as stated above. Techniques to make amino acids are standard procedures and obvious to one of ordinary skill in the art as stated above. One of ordinary skill in the art would use materials derived from ordinary resources and are by their nature not derived from genetically modified organisms. It appears to the Examiner that Applicant is now labeling these ordinary resources as "non-GMO". In the absence of clear and convincing evidence to the contrary, for example that these resources are obtained from genetically modified organisms, the Examiner maintains the rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616
May 02, 2006

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600